



Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1028

Protection of Human Subjects

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: On September 8, 2015, the federal departments and agencies that are subject to the Federal Policy for the Protection of Human Subjects (referred to as the “Common Rule”) published a notice of proposed rulemaking (“NPR”) amending the Common Rule. Through this proposed rule, the Consumer Product Safety Commission (“CPSC” or “Commission”) proposes to adopt the Common Rule NPR and solicits public comment on the proposal.

DATES: Comments must be received no later than 5 p.m. on December 7, 2015.

ADDRESSES: You may submit comments, identified by docket ID number HHS-OPHS-2015-0008, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Enter the above docket ID number in the “Enter Keyword or ID” field and click on “Search.” On the next Web page, click on “Submit a Comment” action and follow the instructions.
- *Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions] to:* Jerry Menikoff, M.D., J.D., OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Hope E. J. Nesteruk, Human Factors Engineer, Division of Human Factors, Directorate for Engineering Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2579; email: hnesteruk@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 18, 1991, the Department of Health and Human Services (“HHS”) issued a rule setting forth the Common Rule requirements for the protection of human subjects. (56 FR 28003). The HHS regulations are codified at 45 CFR part 46. At that time, 14 other agencies, including the CPSC, joined HHS in adopting a uniform set of rules for the protection of human subjects identical to subpart A of 45 CFR part 46. The Common Rule is codified in the CPSC’s regulations at 16 CFR part 1028. The basic provisions of the Common Rule include, among other things, requirements related to the review of human subjects research by an institutional review board, obtaining and documenting informed consent of human subjects, and submitting a written assurance of institutional compliance with the Common Rule.

On September 8, 2015, (80 FR 53933), HHS, on behalf of many of the same agencies that were signatories to the original Common Rule, proposed revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was promulgated as a Common Rule in 1991. The Common Rule NPR seeks comment on proposals to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. The participating departments and

agencies proposed these revisions to the regulations because they believe these changes would strengthen protections for research subjects while facilitating important research.

The full description of the proposed revisions to the Common Rule is provided in the Common Rule NPR at 80 FR 53933. Although the CPSC is a signatory to the original Common Rule, the CPSC's procedural requirements require Commission deliberation and vote on new rulemaking matters. Due to HHS's expedited schedule regarding publication of the Common Rule NPR in the *Federal Register*, the CPSC was not a signatory of the Common Rule NPR. However, through this proposed rule, the Commission proposes to adopt the Common Rule NPR and solicits comment on the proposal.

II. CPSC's Proposed Regulatory Text

CPSC's current regulations on the protection of human subjects are the regulations promulgated by all of the departments and agencies subject to the Common Rule, as codified under the CPSC's regulations at 16 CFR part 1028. For the reasons provided in the Common Rule NPR (80 FR 53933), the CPSC would adopt the amended regulatory text provided in the Common Rule NPR. Because the CPSC follows the HHS regulations in 45 CFR part 46, subpart A, the CPSC proposes to amend the Commission regulations at 16 CFR part 1028 to cross-reference the HHS regulations in 45 CFR part 46, subpart A.

List of Subjects in 16 CFR Part 1028

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Consumer Product Safety Commission proposes to revise 16 CFR part 1028 to read as follows:

PART 1028 – PROTECTION OF HUMAN SUBJECTS

Sec.

1028.101 Cross-Reference.

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

PART 1028 – PROTECTION OF HUMAN SUBJECTS**§1028.101 Cross-Reference.**

The provisions set forth at 45 CFR part 46, subpart A, concerning the protection of human research subjects, apply to all research conducted, supported, or otherwise subject to regulation by the CPSC.

Dated: September 21, 2015.

Todd A. Stevenson, Secretary,
Consumer Product Safety Commission.

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